

Remarks

In the Office Action, the Examiner noted that claims 1 - 20 are subject to restriction in that as filed, they allegedly cover nine (9) independent and distinctly methods of treating a variety of different unrelated medical disorders caused by different unrelated biological pathways whose treatment thereof would therefore constitute separate,unrelated inventions. In particular, the Examiner has given a eight-way restriction in accordance with 35 U.S.C. 121 as follows:

<i>Inventions</i>	<i>Classification</i>
Group I. Claims 1 – 7 drawn to a method of treating a patient for sleep disorders comprising the administration of 2-cyano-10-(2-methyl-3-methylamino)propyl) phenothiazine compounds of formula I or a salt thereof.	514, subcl. 226.2
Group II. Claims 8,9,16 and 17 drawn to a method of treating a patient for anxiety disorders through the administration of the chemical compounds of formula I.	514, subcl. 226.2
Group III. Claims 8, 10,16 and 17 drawn to a method of treating a patient for mood disorders through the administration of the chemical compounds of formula I.	514, subcl. 226.2
Group IV. Claims 8, 11, 16 and 17 drawn to a method of treating a patient for mixed anxiety-depression disorders through the administration of the chemical compounds of formula I.	514, subcl. 226.2
Group V. Claims 8, 12, 16 and 17 drawn to a method of treating a patient for acute and chronic psychotic state through the administration of the chemical compounds of formula I.	514, subcl. 226.2

Group VI. Claims 8, 13,16 and 17 drawn to a method of treating a patient for addiction to and withdrawal from a substance through the administration of the chemical compounds of formula I.	514, subcl. 226.
Group VII. Claims 8, 14,16 and 17 drawn to a method of treating a patient suffering from extrapyramidal events induced by an anti-psychotic through the administration of the chemical compounds of formula I.	514, subcl. 226.2
Group VIII. Claims 8, 15,16 and 17 drawn to a method of treating a patient suffering from an symptomatic dimension during an acute or chronic psychotic state as a monotherapy through the administration of the chemical compounds of formula I.	514, subcl.
Group IX. Claims 8, 13,16 and 17 drawn to a method for preparing a medicament through the mixing the chemical compounds of formula with other additional pharmaceutically acceptable actives, excipients, fillers.	514, subcl. 226.2

As indicated above, through this response, Applicants provisionally elect invention Group I **with traverse**, namely, claims 1 – 7 drawn to the a method of treating a patient for sleep disorders comprising the administration of 2-cyano-10-(2-methyl-3-methylamino)propyl) phenothiazine compounds of formula I or a salt thereof. However, the Examiner's imposition of the nine-way restriction is respectfully traversed below.

Applicants submit that this nine-way restriction as imposed by the Examiner is improper based on the following grounds:

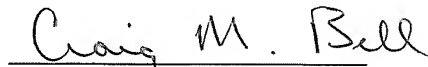
1. There is no undue burden on the Examiner to search for all of the claims as they are believed to be in same or similar classifications.

First, Applicants respectfully submit that a search of all of the originally claimed methods of treatment for sleep disorders, anxiety, mood and psychiatric disorders, etc., recited in claims 1-20 prior to the restriction should not impose any undue burden on the Examiner. In support of this assertion, Examiner's attention is directed to the Table shown above, which lists all nine (9) restricted inventions. Despite their same search classifications in the U.S.P.T.O., the Examiner has not provided any reasoning or evidence to justify the alleged undue burden that will be imposed if these methods for the treatment of various central nervous system disorders are searched together nor is there any justification provided to support the assertion that the nine (9) disorders have different unrelated biological pathways, different target cells and different unrelated etiologies, etc., and therefore they will have different modes of operation and physiological effects. Applicants respectfully submit that such assertions must be provided in the Office Action in support of any imposition of a restriction requirement under 35 U.S.C. 121.

Moreover, it is also respectfully submitted that all nine (9) methods of treatment comprise the administration of the same active pharmaceutical agent to a patient for the treatment of a central nervous system (CNS) disorder. The therapeutic target and the compound administered for treatment is the same in each and the fact that the disorders treated are albeit somewhat different in view of their outward physiological manifestations will not change this. All nine (9) restricted inventions are in the same search classification and are thus related and therefore the methods of treatment comprise the same invention. As a result, it is respectfully submitted that all nine (9) inventive groups can be searched together and thereby impose no undue burden on the Examiner. Therefore, Applicants by their Attorney respectfully submit that all inventions be rejoined in this manner and the above-referenced restriction be withdrawn.

In the event the Examiner wishes to contact the undersigned regarding any of the aforementioned issues or claims, please call (collect if necessary) the telephone number listed below. Applicants believe that there are no fees due for this response. However, if the Examiner deems that fees are due, please charge these fees to Deposit Account No. **18-1982** for sanofi-aventis, U.S. LLC, Bridgewater, NJ. Please credit any overpayment to Deposit Account No. **18-1982**.

Respectfully submitted,

A handwritten signature in cursive script that reads "Craig M. Bell". The signature is written in black ink and is positioned above a horizontal line.

Craig M. Bell
Registration No. 31,812
Attorney for Applicants

sanofi-aventis U.S. LLC
U.S. Patent Operations
Route #202-206 / P.O. Box 6800
MAIL STOP: BWD-303A
Bridgewater, NJ 08807-0800
Telephone: 908-231-2387
Telefax: 908-231-2626